

## **REMARKS**

Claims 1-4 and 6-36 are currently pending. Reconsideration of the application in view of the current claims is respectfully requested and further in view of the following Remarks.

### **I. REJECTION UNDER 35 U.S.C. 112, SECOND PARAGRAPH**

The Examiner rejected claims 1-4 and 6-36 under 35 U.S.C. § 112, second paragraph. In particular, the Examiner asserts that certain claim elements in independent claims 1, 18, 19 and dependent claim 12 lacked antecedent basis or were vague and indefinite. Claims 1 and 12 are amended herein to resolve issues concerning antecedent basis.

However Applicants respectfully decline to amend the claims further with respect to other claim elements and limitations pointed out and considered by the Examiner to be vague or unclear. For example, the use of the terms “microdroplet” and “liquid droplet” in these rejected claims are clear on their face and no further clarification is deemed warranted. The Examiner provides no technical basis to support her contention as to what should or should not be considered a droplet or microdroplet. Pursuant to MPEP 2173.02: The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. The claims presented by Applicants, when read in the context of the disclosure and the teachings of the prior art would give one of ordinary skill in the art sufficient detail to understand the scope of the invention as required under § 112. Accordingly, Applicants believe this portion of the rejection under 35 U.S.C. 112, second paragraph is improper and should be removed.

### **II. CLAIM REJECTIONS UNDER 35 U.S.C. § 102(B)**

In order for Applicants’ claims to lack novelty under 35 U.S.C. § 102 (*i.e.*, be anticipated), each and every element of the claimed invention must be disclosed in a single prior art reference. A prior art reference anticipates a claim *only if* the reference discloses, either expressly or inherently, every limitation of the claim. A ground of rejection based on a feature allegedly inherent in the prior art must have a basis

in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. *See* Manual of Patent Examining Procedure § 2112. (2005).

The Patent Examiner bears the burden of demonstrating that Applicants' invention is anticipated by the reference relied on in the Examiner's reasons for rejection.

For the following reasons, Applicant believes the Examiner has not met this burden.

**A. Rejection of claims 1, 8 and 12 as anticipated by Castor et al.**

The Examiner rejected claims 1, 8 and 12 as being anticipated by Castor et al. (U.S. Patent 5,776,486). The Examiner asserts that "Castor et al discloses a method and apparatus for making liposomes contains (sic) hydrophobic drugs."

Applicants' claims are directed toward an aqueous suspension of microdroplets suitable for intravenous delivery. Castor does not teach or suggest an aqueous suspension of microdroplets. For example, in Example 12 (col. 30), Castor discusses the disadvantages of an aqueous solution stating "Liposomes maintained in aqueous suspension may aggregate, fuse, or leak their contents."

Accordingly, Castor does not teach and suggest each and every limitation of Applicants' claims. Therefore, the claims are not anticipated by Castor and the rejection should be withdrawn.

**B. Rejection of claims 1-4, 8 and 12-17 as anticipated by WO 95/08986**

The Examiner rejected claims 1-4, 8 and 12-17 as being anticipated by WO 95/08986. The Examiner asserts that "WO '986 discloses multilamellar vesicles comprising camptothecin."

Applicants' claims are directed toward an aqueous suspension of microdroplets suitable for intravenous delivery. WO '986 does not teach or suggest an aqueous suspension of microdroplets. Therefore, the claims are not anticipated and the rejection should be withdrawn.

**III. CLAIM REJECTIONS UNDER 35 U.S.C. § 103(A)**

During patent examination the PTO bears the initial burden of supporting a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, it is necessary for the Examiner to present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art would have been led to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention. Mere identification in the prior art of each element is insufficient to defeat

patentability of the combined subject matter. There must also be some suggestion or motivation to modify the reference or to combine reference teachings. *See* MPEP § 2142. Thus, there must be some positive, concrete evidence which gives a logical reasoning which justifies a combination of references. Further, Applicant's explanation of how the invention works does not render obvious that which is otherwise unobvious. Finally, there must be a reasonable expectation of success and the references must teach or suggest all of the claim limitations.

In practice, this requires that the Examiner explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious. Further, the factual inquiry of whether to combine references must be based on the objective evidence of record. Failure to meet that burden is a basis for the Board to overturn the obviousness rejection. The Examiner cannot simply use Applicant's teaching to show that a person of ordinary skill would have been led to the combination of references. Similarly, the Examiner cannot provide conclusory statements supporting the rejection. As the Federal Circuit has noted the motivation-suggestion-teaching requirement protects against the entry of hindsight into the obviousness analysis.

A prima facie case of obviousness can be rebutted if the Applicant can show that the art teaches away from the claimed invention.

Applicants believe the Examiner has not met his burden under § 103 for the following reasons:

A. **Claims 1-4, 6-8, and 12-17 have been rejected under 35 U.S.C. § 103 over Wallach in view of Gregoriadis in further view of Burke**

The Examiner rejected claims 1-4, 6-8, and 12-17 under 35 U.S.C. 103(a) as being unpatentable over Wallach (U.S. Patent 5,628,936) in view of Gregoriadis (Liposome Technology, Vol. 3, p. 21) further in view of Burke (U.S. Patent 5,552,156). Applicants respectfully traverse the Examiner rejection based on the following reasons.

The Examiner asserts that Wallach et al. teaches a hybrid paucilamellar lipid vesicle (PLV) containing a phosphor glycolipic and a surfactant in the lipid bilayer." However, as stated above, Applicants' claims are directed toward an aqueous suspension of microdroplets suitable for intravenous delivery.

WO '986 does not teach or suggest an aqueous suspension of microdroplets. Nothing in Wallach, Gregoriadis or Burke, teach or suggest the aqueous suspension of microdroplets claimed by applications. Accordingly, Applicants respectfully state that none of these references teach or suggest the claimed

invention or aqueous suspensions of microdroplets. Since none of the cited references teaches or suggests the claim limitations, withdrawal of this rejection is respectfully requested.

**B. Claims 9-11 and 18-36 have been rejected under 35 U.S.C. § 103 over Wallach in view of Gregoriaris in view of Burke and further in view of WO 99/61001**

The Examiner rejected claims 9-11 and 18-36 under 35 U.S.C. 103(a) as being unpatentable over Wallach in view of Gregoriaris cited above and further in view of Burke cited above, further in view of WO 99/61001. For all the reasons mentioned above, these claims are also allowable as they contain similar limitations. Applicant respectfully requests the withdrawal of the obviousness rejection under 35 U.S.C. 103(a).

**C. Claims 6-7, 9-11, 18, 20-27 and 30-33 have been rejected under 35 U.S.C. § 103 over WO 95/08986 and in view of WO 99/61001**

The Examiner rejected claims 6-7, 9-11, 18, 20-27 and 30-33 under 35 U.S.C. 103(a) as being unpatentable over WO 95/08986 in view of WO 99/61001. For all the reasons mentioned above, these claims are also allowable as they contain similar limitations. Applicant respectfully requests the withdrawal of the obviousness rejection under 35 U.S.C. 103(a).

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### CONCLUSION

For the foregoing reasons, Applicants request the Examiner allow claims 1-4 and 6-36 and advance the application to issuance.

### FEE AUTHORIZATION

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. **23-2415** (Docket No. 12636-898).

Respectfully submitted,

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